NFPA
The Food Safety People

NATIONAL
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ASSOCIATION

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November 27, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, Maryland 20852

Re: Docket No. 00D-1539
Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures Maintenance of Electronic Records

Dear Sir or Madam:

The National Food Processors Association (NFPA) is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

Overview

Addressing the 21 CFR Part 11 long-term retention requirements has proven to be every bit as challenging as expected to identify the key technical issues and considerations to achieve realistic and pragmatic solutions to the preservation of and access to e-Records. Ideally, the requirements and implementation of an e-Archive should make good business sense and address business, legal and regulatory needs leading to a holistic approach rather than fragmented solutions.

The food industry understands and is fully committed to continued access to, and the preservation of accurate, complete and trustworthy e-Records for business, legal and regulatory needs for many years. The food industry also understands that while there are manageable steps that enable industry to make significant progress toward meeting the requirements today, we also recognize that the technology for permanent long-term solutions does not exist. Based on industry experience, we expect implementation to come at significant cost to the regulated industries.

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NFPA offers the following comments to FDA for the purposes of discussing the critical technical issues that will guide implementation, as technology evolves.

Phased-In Implementation

A phased-in implementation approach should be considered. Any one technical issue alone can be extremely challenging and complex in its own right, but the combination of key issues makes meeting the Part 11 long-term retention requirements very demanding and costly to Industry and subsequently the public. Industry's experience to date strongly suggests that the success of our meeting all of the business regulatory retention requirements, for the long term, will be very complex, problematic and extremely costly. Consequently, we question the cost-benefits of requiring all aspects of Part 11 being implemented at the same time, versus a phased-in approach. We urge you allow the industry the benefit of phasing in these new requirements.

Migration/Retention

The 21 CFR Part 11 Industry Coalition's work reaffirms the value of the emerging Technology Neutral File Formats (TNF) for electronic documents and de facto database standards from leading vendors. When the e-Record retention period is greater than the useful life of the technology, and the e-Records are not to be migrated to a modern platform, a TNF or leading vendor database format offers the greatest likelihood of long- term readability, but may not preserve all the technical attributes of the original e-Records. E-Record "Viewers" of the original format may overcome this issue, but are expected to be costly to develop and maintain.

Migration (recurrent transfers) of e-Records from one technology (hardware and/or software) to the next generation is the most common method known today to ensure that records are usable and trustworthy for as long as necessary and preserve processing capabilities. Where the need exists to provide only e-Copies in human or computer readable form, 'views' may be sufficient. Both are processes requiring continual reinvestment. Present experience indicates this required reinvestment to be typically in the 7 to 10 year range due to technical obsolescence, and at significant costs attributed to the necessary IT resources. Where only relatively short term (3-5 years) retention periods are required retaining the legacy environment, or subset, may provide a viable alternative.

NFPA endorses the use of mainstream technology products based on open standards or leading database vendors. For electronic documents there are two primary choices in focus today, PDF (portable document format) and XML (Extensible Markup Language). These are widely accepted practices with a large user base and are based on published specifications. For data, other than ASCII, which is limited, and possibly XML including its many extensions (e.g. SVG), de facto standards from leading database vendors prevail.

Long Term Retention

The issues of long-term retention have many inherent complexities, including the potential loss of usability for e-Records. The focus must be on the capability to securely retain and retrieve the content of the e-Records and to understand their context beyond the useful life of the technology in which any retained e-Record was created/maintained. The key issues that were developed concerning e-Record retention and retrieval are summarized below:

1. **No Guaranteed Solutions and Limited Commercially Available Solutions:** there is no known solution available today for permanent preservation of trustworthy e-Records. All require substantial ongoing efforts consistent with the retention periods. All current options require, in varying degrees, significant ongoing maintenance. These must be routinely maintained and periodically upgraded, typically in the 7-10+/- year range, to preserve the basic ability to create complete and accurate e-Copies in human and computer readable form. In cases where proprietary technology is used and vendor technical specifications are not available to the user, access may be limited to the life of the technology. It is clear that long-term retention and access will be a costly and a continually evolving process in order to satisfy both business and regulatory requirements. A range of solutions is likely to be applied case-by-case.

2. **Evolving e-Record Formats:** can be expected to continue as technology advances and may result in process incompatibility. TNF based on published "open standards" are expected to be very helpful. However, TNF are not considered the complete answer as preservation in these formats could yield loss of functionality, different "look and feel," possible loss of "meta data" and could become obsolete due to vendor dependence.

3. **Impact of Migration and/or System Retirement**: may result in the loss of readability and/or process capabilities. Some allowance should be made for processing variance (e.g., changes in data calculation at the nth decimal place) arising from the reprocessing in new/different software or hardware platforms due to migration or system retirement. The fundamental objective of the e-Archive is to secure and preserve the essential meaning of the information in the electronic records, in that it would be viewed by experts in the field as equivalent to the original in the context of its stated, actual or intended use. Companies and government agencies retire software and hardware through a documented process based on sound business decisions. As a result, functional capabilities that create/maintain/analyze e-Records may vary in the replacement computer systems or even be lost completely. NFPA agrees with FDA that it is unrealistic to retain obsolete hardware, software, media, skills, etc. and expect to be able to reconstruct the original functional environment. The ability to provide accurate and trustworthy electronic copies in human and computer readable form will prove to be an ongoing challenge.

4. **Cost and Time to Comply:** the costs and benefits as discussed in Part 11 did not seem to address the costs to maintain electronic records for long retention periods. Industry experience and belief is that these costs and time to comply are likely to be significant.

5. **Impact on e-Signatures:** Among several techniques for identification of an individual, the Part 11 rule recognizes the use of cryptographic methods of originator authentication that validate the identity of the signer. Over time, the use of encryption algorithms to revalidate the integrity of the data assumes that there is no change in the underlying bit streams of e-Records that are signed. Such changes do occur when e-records are migrated from an older format to a newer one. Thus, adequate documentation of the records' integrity, including trust certification and an audit trail of actions, created at or near the time of signing is recommended over maintaining the technical ability to revalidate digital signatures as far into the future as may be required.

Summary

NFPA values the effort that the Agency is putting toward clarification of 21CFR Part 11 and appreciates the opportunity to share the food industries main concerns so that a workable solution is achieved and the food safety and public health safety are preserved.

Thank you for providing this opportunity to comment.

Sincerely,

Sia Economides
Senior Scientist

Allen Matthys, Ph.D.
Vice President, Federal & State Regulations

Comment Form

				Date November, 2002	Document Maintenance
Comment By	**Reference Section**	**Paragraph/ Figure/ Table Line No.**	**Proposed Change**	**Comment/ Rationale**	
	General			Guidance should recognize that there are no guaranteed permanent technical solutions and limited commercially available solutions to meet the long-term retention requirement. Further, the guidance should include the FDA's current thinking on ways to achieve a migration without unnecessary costs to industry.	
	2. Intent of Part 11	99	"compatible with FDA's public health responsibilities" should be changed to "generally equivalent to paper records and handwritten signatures executed on paper."	No need to substitute new wording for the wording in the original rule. Does not confer clarity and introduces new areas of debate on interpretation. Stick with the original wording.	
	4.1 What Does part 11 Require	172	Change "Accordingly, the signature manifestation information, associated with an electronic record that is subject to this requirement, must be maintained for the duration of the record retention period. " To ""Accordingly, the printed name of the signer, the date and time of signing and what the signature means, associated with an electronic record that is subject to this requirement, must be maintained for the duration of the record retention period."	It is constructive to describe what constitutes the "signature manifestation information" expected	
	4.1	181-2	Delete "authentic, and compatible with the FDA's public health responsibilities."	How is "authentic" different from "trustworthy". Why introduce a new term to be debated? Why the "compatible..." phrase that does not shed any more clarity and introduces a new subject of debate on interpretation?	

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	5.2, Factors That Might Affect The Reliability ..	210	Change "You should identify and control factors that could potentially affect the reliability of electronic records during their records retention periods." To: "You should identify and, to the extent possible, control factors that could potentially affect the reliability of electronic records during their records retention periods.	It is important to recognize that not all factors identified may be controllable.	
	5.3 Continued Availability And Readability Of Electronic Record Information Should Be Ensured.	245	Add at end of last sentence "For the purpose of long term retention, electronic records may be retained in a format that differs from the original, which may include a format that offers dependence on technology and offers a broader probability for readability.	It is important to recognize the merits de-facto database standards and 'Technology Neutral Formats' offer for the long-term retention of required electronic records.	
	5.5 The Ability To Process ..... Should Be Preserved.	258	Change "Throughout the records retention period, the ability to process information in an electronic record should not diminish.: To "Throughout the records retention period, electronic record should be maintained in a manner that allows the electronic record's information to generate copies in human and computer readable from that are suitable for FDA inspection, review, and copying."	Maintaining process capability of the old system is substantial expansion of scope of Part 11 functional requirements that should go through the proper FDA rule making process rather than being introduced via guidance. Further, this is unrealistic to achieve in some cases. For example, the ability to process information may be lost as systems are retired or become obsolete.	

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	5.5 The Ability To Process ..... Should Be Preserved.	273	Change "For example, if you could automatically search for words in the text of an electronic record, sort or find values in a table, or perform calculations in a spreadsheet, you should be able to process information in a like manner for the electronic record over the entire records retention period. This ability (or functionality) derives largely from the hardware and software used to extract information from the electronic record, as well as the electronic record format itself. You should include this ability among your specifications in your procedures and controls." To "Throughout the records retention period, electronic record should be maintained in a manner that allows the electronic record's information to generate copies in human and computer readable from that are suitable for FDA inspection, review, and copying."	Maintaining process capability of the old system is substantial expansion of scope of Part 11 functional requirements that should go through the proper FDA rule making process rather than being introduced via guidance. Acceptable alternatives are addressed in the predicate rules. For example in the GMPs section 211.180 (d) and the GLPs section 58.195 (g), the rule states "Records required by this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records." This clearly shows the intent to retain the information and does not require reprocessing." Requirement for reprocessing should be limited to those stated in a predicate rule and not introduced through Part 11 guidance(s).	
	5.6 The Coping Process Should...	291	"Draft Guidance For Industry – Not For Implementation 12"	Appears to be extraneous text that is confusing	

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	6.2.1.3 Electronic Record Integrity Attributes Should Be Preserved.	422	States "Where a migration, in effect, creates a new electronic record (by transforming the old electronic record) then, per section 11.10(e), the audit trail for the migrated electronic record would have to cover this creation."	Given the migration from the old and new systems is documented this appears to be an unnecessary step and one that is not typically supported by commercial software. Thus adding to the effort and cost of migration with limited incremental value.	
	6.2.1.4 The Ability To Process Information In Electronic Records Should Be Preserved.	442	Change "In the migration approach, the new computer system should enable you to search, sort and process information in the migrated electronic record at least at the same level as what you could attain in the old system (even though the new system may employ different hardware and software). To "In the migration approach, the new computer system should be capable of making copies of the records in human and computer readable form which can be searched, sorted and processed by the FDA.	While there may be similarities, maintaining process capabilities of the old system(s) in a new is a substantial expansion of scope of Part 11 functional requirements that should go through the FDA rule making process rather than being introduced via guidance. Further and unrealistic to achieve in some cases. For example, the old system may not have the ability to search, sort or process information in the way desired. Further e-Records may not be migrated and the ability to process information may be lost as systems are retired or become obsolete.	
	6.2.1.5 Unavoidable Differences And Losses Should Be Accounted For....	454	Insert sentence after "presented." "The fundamental objective of the migration is to preserve the essential meaning of the information as judged by experts in the field to be equivalent to the original in the context of its stated, actual or intended use.."	Migration to new systems may result in changes in appearance as well as analytical result calculation precision from the original system. Recognizing this it is important that the essential meaning of the information not change and that only that information relevant to essential meaning need be migrated.	

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	6.2.1.5 Unavoidable Differences And Losses Should Be Accounted For....	471 - 473	Change: "Just prior to performing the electronic record migration a trusted third party from outside of the organization that has some responsiblity for the electronic record verifies the digital signature using the old system methods:" To: "Just prior to performing the electronic record migration a trusted third party verifies the digital signature using the old system methods. The trusted third party should be independent from the organizational unit responsible for the electronic record and may be an independent service provider from outside the corporation regulated by the FDA.	Current sentence is confusing. Clarification is needed on who is an acceptable 3rd party.	
	6.2.1.5	478	Replace line 478 with: "The migrated records must maintain the integrity of the association of signators (people) and records. The above trusted third party then applies a new digital signature (their own)	It must be clear that you are not migrating the signature itself, but rather migrating a representation of the fact of the signature and adding a new signature of testimony by a trusted third party.	
	6.2.1.5 Unavoidable Differences And Losses Should Be Accounted For....	495	States "An electronic record that supplements the migrated electronic record should explain the correlation between old and new color representations, so that the reader would correctly interpret the information"	Given the differences between the old and new systems are documented this appears to be an unnecessary step and one that is not typically supported by commercial software. Thus adding to the effort and cost of migration and offering limited incremental value.	

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		497-499	Replace the entire sentence "However... authenticity." With: "The text (that referred to the colors) may be altered to be consistent with the new colors."	Transcribing of the text to refer to the new colors is required to preserve the essential meaning of the record in a manner that is easily understood. Requiring literal text be preserved and to be understood by humans in a convoluted fashion, especially after multiple migrations, could lead to human error of serious consequence. Migrations of text need not be any more literal than migrations of numbers that may change in literal representation from one system to the next. The key determining factor should be whether the migrated record preserves the essential meaning of the original record, i.e. judged by experts in the field to be equivalent to the original in the context of its stated, actual or intended use. Any such transcription can be documented as part of the migration process. Furthermore, this requirement is not typically supported by commercial software.	